to coordinate AIDS Control activity in the country.

(2) 34 surveillance centres have been established in the country to screen high risk group.

(3) Ali these centres have been provided with diagnostic reagents and equipment package have also been provided to most of them.

(.4) Restrictions have been Imposed for import of blood and blood products without AIDS clearance certificate.

(5) All the State Health Authorities! Hospitals STD clinics have been alerted to be vigilant,

(6) Ali the blood tanks have been instructed to screen the professional blood doners.

(7) Ali the State Health Authorities have been advised to ensure strict sterilisation practices in' hospitals and c!inics and to use pre-sterilised disposable syringes and eee'dles as far as possible.

(8) Guidelines have been sent to all the . State Health Authorities for Health » care personnel.

(9) All the mass media channels have been involved in educating the people on AIDS, its nature, transmission and Pre vention.

(10) Foreigners other than those working in Missions including foreign students likely to, stay in India for more than one year will be required to undergo AIDS test on arrival. However, foreign students who are already in India, when admission is sought will not be required to undergo AIDS test..

Guidelines for New Drags, Vaccines and Combinations

510. SHRI BHUBANESWAR KALITA; Will the Minister- of HEALTH AND FAMILY WELFARE be pieased to state:

(a) whether it is a fact that Government have issued guidelines defining new drugs, new vaccines and combination of one or ntorc drugs;

(b) if so, what are the details $_0$f the same;

(c) whether it is a fact that according to these guidelines the States Drugs • norities- are not authorised to issue any permission for new drugs, new vaccines and new combination of drugs and vac cines;

(d) names of new drugs, new vaccines and new combination of drugs and vaccine allowed by each State Drug Authorities from 1st April, 1986 to 30th June, 1987;

(e) what are the basis on which these permissions have been granted;

(f) whether it is a fact that neither any clinical trial nor any published data was submitted; and

(g) what steps have been taken to suspend the marketing of these products till Government are satisfy about safety,' efficiency arid other aspects?

' THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE); (a) Yes, Sir.

(b) In the guidelines what constitutes a new drug has been defined, the details of preclinical data required for granting clinical trial permission in the country have been enumerated, the details of data equired for granting marketing permission of a new drag in the country have been given and the various formalities and rules pertaining to import and manufacture of new drugs in the country have been quoted from the Drugs and Cosm'etics Act.

(c) to (f) Since the guidelines are not yet statutory some State Drug Control Authorities in consultation with their local cxperts licence combinations of already marketed drugs and vaccines as 'hey did not strictly consider such combination as new drugs.

The names of combination of drugs and vaccines licensed for marketing by the State Licensing 'Authorities as avail-

able with the Govt. is given in the annexed statement. *({See* below)

*

(g) Government has initiated steps to make the guidelines on introduction of new drugs including the definition of the terms 'new' drug as statutory. The combinations cleared by the State Licensing Authorities will be reviewed by a sub-committee constituted by the Government to advise Government on the continued marketing of formulations including combinations moving in the Tndian market on the basis of safety efficacy and rationality.

Statement

Combination of dr nis cleared b- the state drugs control Author hies

S-No.	Nam: of the product	Coinposition
1	Arthril Capsules	Kotoprogen B.P. Propyphenazone B.p. Terbyutaline Sulphate B.P. Hydexythul thephylline LP. Grain Phenazen B.P.C.
2	Tersiphyl Tablets	
3	Kstodol Capsula	Paracetamol LP. Ketoprofen B.P.
4.	"Tenccbetic 50 Tablets	Atenolol U.S.P. Ghlorthalidenc U.S.P.
5	Golgesic Tablets	lbuprofen B.P. Analgin I.P.
6.	Promagssic Tablets	Ibuprofen B.P. Mefenamic Acid B.P.
7	' Antakid forte Tablets	Magaldrate U.S.P. Simethicome U.S.P.
8	Terbutaline Sulphate with Etofyline Tablets 'Torphylin Forts'	Terbutaline Sulphate Etofyline B.P.
9	Terbutaline Sulphate with Taiaraeinolono Tablets	TerbmallineSulphateB.P. Triamcinolone U.S.P. Colour : Sunset Yellow PCF
10 O	Calmpairt-5	Dicyclomine Mel. B.P. Mefanimic Acid B.P.
11	Veraptim-L Tablets	Verapemil Hydrochloride B.P. Lorazepam
12	Tromaril-P Tablets	Enfemamic Acid Paracetamol I.p.
13	Torhexin Tablets	Torbutaline Sulphate B.P. Bromhaxin Hydrochloride B.P.
14	Rectal (Tiblets of Tinidazole and Covti i-moxazole)	Tinidazole I.P. Trimethoprim B. P. Sulphamethaxazole S.p.
15	Hexabutol Tablets	EtrnbutalHCLLP. Dsoriazid LP. Vit. B 6 I.P.
16	Meftalab Tablets	Mefamamic Acid B.P. Chlormezenon
17	Repress Tablets j	Metroprolol Tertrate Hydrochlonotheuidc
18	Fluzyrae Ointment	Fluecinelone Acctenoide B.P. Neamcin Sulphate I P. Tripsin and Chymetrypcin concentrate Equl. to tryptic activity to 4 mg. of Trypsin U SF

S.No.	Name of the product	Composition
19	Inzol Tablets	Indepamide Metroprolol Tartrate USp
20	Silverex Cream	Silver Sulphediazine Chiorhaxadine Gluconate BPC
21	R-laxdol Tablets	Mefanamic Acid B.P. Diamepan I.P.
22	Relaxccol Forte Tablets	Mafonamic Acid B.P. Diaxepam I.P.
23	Imibutanol DS Tablets	Ethambutal Hcl. B.P. Isoniaid I.P.
24.	-V'lonithan Tablets	Clonidine HcL B.P. Chlorthalidone I.P.

The House then adjourned at one minute past three of clock till eleven of the clock on Thursday, the 30th July, 1987.

MGIPND—L—724 RS—10-10-87—400.